

REMARKS

The final Office Action of July 3, 2008, has been received and reviewed.

Claims 1-38 are currently pending and under consideration in the above-referenced application, each standing rejected.

Reconsideration of the above-referenced application is respectfully requested.

Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 24-30, 36, and 37 have been rejected under 35 U.S.C. § 112, second paragraph, for reciting subject matter that is purportedly indefinite.

The Office has rejected each of claims 24-30, 36, and 37 for purportedly being limited only to features of an unclaimed component; *i.e.*, of a respiratory flow component to which the transducers of claims 24-30, 36, and 37 are configured to be removably secured. While several of the rejected claims mention features of the unclaimed respiratory flow component, such these recitations merely provide context for the additional elements of the transducers of claims 24-30, 36, and 37.

In this regard, claim 24 recites that the transducer includes “at least a portion of a temperature control component.” Claim 25 recites that the temperature control component of claim 24 “includes a heater component.” Claim 26 recites that the temperature control component is “exposed through the transducer.” Claim 27 recites that the heater component of claim 25 is “*configured* to contact [a] thermal capacitor” (emphasis supplied). Claim 28 recites that the heater component of claim 25 includes “a thermally conductive component” and “a thick film heater.” Claim 29 also depends from claim 25 and recites that the transducer includes “a temperature control associated with [the] heater component.” Claim 30 recites that the transducer further includes “a temperature sensor.”

Independent claim 36 has been rejected for the recitation “and being substantially stable for a period of at least about eight hours.” Office Action of July 3, 2008, page 3. It has been asserted that this recitation is “highly ambiguous as to what the structural element is with respect to the flow component.” *Id.* Upon reading independent claim 36, it would immediately be clear to one of ordinary skill in the art that it is the *detector*, not any portion of a respiratory flow

component, that is “substantially stable for a period of at least about eight hours.” Likewise, one of ordinary skill in the art would immediately appreciate that it is the *detector* of the transducer of claim 37, not any part of a respiratory flow component, has a stability of about \pm 2 torr over eight hours at an atmospheric oxygen concentration.”

As the plain language of each of claims 24-30, 36, and 37 readily conveys to one of ordinary skill in the art various features of the claimed transducers, it is respectfully submitted that one of ordinary skill in the art would find each of these claims to be definite. It is, therefore, respectfully submitted that each of claims 24-30, 36, and 37 complies with the definiteness requirement of the second paragraph of 35 U.S.C. § 112.

Furthermore, nothing in the patent laws, the patent rules, or the M.P.E.P. precludes “structural limitation[s,] the definition[s] of which [are] dependent upon a particular assembly” of the claimed transducer to an unclaimed respiratory flow component. Office Action of July 3, 2008, page 3.

Withdrawal of the 35 U.S.C. § 112, second paragraph, rejections of claims 24-30, 36, and 37 is respectfully solicited, as is the allowance of each of these claims.

Rejections under 35 U.S.C. § 103(a)

Claims 1-38 stand rejected under 35 U.S.C. § 103(a).

There are several requirements in establishing a *prima facie* case of obviousness against the claims of a patent application. All of the limitations of the claim must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 985 (CCPA 1974); *see also* MPEP § 2143.03. Even then, a claim “is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *KSR Int’l Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007). The Office must also establish that one of ordinary skill in the art would have had a reasonable expectation of success that the purported modification or combination of reference teachings would have been successful. *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). There must also be “an apparent reason to combine the known elements in the fashion claimed by the patent at issue.” *KSR* at 1396. That reason must be found in the prior art, common knowledge, or derived from the nature of the problem itself, and not based on the

Applicant's disclosure. *DyStar Textilfarben GmbH & Co. Deutschland KG v. C. H. Patrick Co.*, 464 F.3d 1356, 1367 (Fed. Cir. 2006). A mere conclusory statement that one of ordinary skill in the art would have been motivated to combine or modify reference teachings will not suffice. *KSR* at 1396.

Stanley in View of Knodle

Claims I-10, I3-15, and 17-37 stand rejected under 35 U.S.C. § 103(a) for reciting subject matter which is assertedly unpatentable over the subject matter taught in U.S. Patent 3,725,658 to Stanley et al. (hereinafter "Stanley"), in view of teachings from U.S. Patent 4,914,720 to Knodle et al. (hereinafter "Knodle").

Stanley teaches an integral side stream monitoring apparatus that employs luminescence quenching technology for detecting changes in oxygen present in diverted respiratory samples. As evidenced by FIG. 2 of Stanley, a source 27 and detector 28 are positioned on the same side of a transparent tube 24, but are oriented toward different areas of the tube 24, toward a sensor film 25 on an opposite side of the tube 24. *See also*, col. 6, line 55, to col. 7, line 5. These separate areas on the surface of the tube 24 toward which the source 27 and the detector 28 are oriented are separated by an opaque plate 29. FIG. 2; col. 6, lines 63-65. This arrangement is intended "to eliminate spurious readings." Col. 6, lines 63-65.

Knodle teaches an infrared carbon dioxide cuvette that is configured for placement directly along a breathing tube. Accordingly, the cuvette of Knodle is part of a so-called "mainstream" sensor. A complementarily configured transducer of that sensor is configured for assembly with and disassembly from the cuvette.

It is respectfully submitted that there are several reasons that a *prima facie* case of obviousness has not been established against any of claims 1-10, 13-15, or 17-37.

First, it is respectfully submitted that neither Stanley nor Knodle teaches or suggests each and every element of several claims of the above-referenced application.

Again, the teachings of Stanley are limited to oxygen sensors that lack transducers that are separate from and configured for assembly with respiratory flow components. Rather, the source 27 and detector 28 of Stanley are positioned so as to be oriented toward different areas

(which are separated by an opaque plate 29) of a tube 24, not toward *the same area* of an exterior surface of a window, as required by each of independent claims 1, 36, and 38, as proposed to be amended.

The transducers taught in Knodle are configured to monitor carbon dioxide by directing infrared radiation completely through a cuvette so that the amount of attenuation of the radiation can be determined to provide an indication of the amount of carbon dioxide in a respiratory sample. Thus, the source and detector of Knodle are not oriented toward *the same area* of an exterior surface of a window.

As neither Stanley nor Knodle teaches or suggests a transducer with a source and detector that are positioned adjacent to one another and that are oriented toward the same area of the same exterior surface of the same window, it is respectfully submitted that the combined teachings of these references do not teach or suggest each and every element of any of amended independent claim 1, amended independent claim 36, or amended independent claim 38.

Furthermore, neither Stanley nor Knodle teaches or suggests a transducer with a source that is oriented toward an exterior surface of a window of a respiratory flow component to direct radiation directly through a thickness of the window to a luminescable composition adjacent to an opposite, interior surface of the window.

Therefore, the Office has not established a *prima facie* case of obviousness against amended independent claim 1, amended independent claim 36, or amended independent claim 38, as would be required to maintain the 35 U.S.C. § 103(a) rejections of these claims.

Claims 2-35 are each allowable, among other reasons, for depending from independent claim 1, which is allowable.

Claim 37 is allowable, among other reasons, for depending from independent claim 36, which is allowable.

Moreover, neither Stanley nor Knodle teaches or suggests a transducer with a detector that is configured to communicate with a processor configured to increase a signal-to-noise ratio of a signal indicative or an intensity of at least one wavelength of electromagnetic radiation emitted by a luminescable composition, as required by claim 3. The teachings of Stanley regarding signal-to-noise ratios are limited to the recognition that a high ratio is desirable.

Stanley and Knodle also lack any teaching or suggestion of a transducer that includes a detector that is configured to communicate with a processor that operates under different processing protocols depending upon the monitored oxygen concentration, as recited in claim 5.

Claims 6 and 7 are directed to allowable subject matter since Stanley and Knodle both lack any teaching or suggestion of a transducer with a detector that comprises a photodiode or a transducer that comprises a PIN silicon photodiode, respectively.

With respect to the subject matter recited in claim 17, neither Stanley nor Knodle teaches or suggests a transducer with a second radiation source that emits at least a calibration wavelength of electromagnetic radiation. The teachings of Stanley are instead limited to calibration of a sensor with gas mixtures including known concentrations of oxygen.

Claim 18, which depends from claim 17, is also allowable since neither Stanley nor Knodle includes any teaching or suggestion of a transducer with a second radiation source that emits calibration radiation that will not cause a luminescable material of a sensor that configured for assembly with the transducer to luminesce.

With respect to the subject matter recited in claims 25-30, even assuming, *arguendo*, that Stanley suggests the desirability of including a temperature control component in a transducer, neither Stanley nor Knodle teaches or suggests a transducer with a heater component that is configured to contact a thermal capacitor upon assembly of the transducer with a respiratory flow component, as recited in claim 25; a transducer with a temperature control component exposed therethrough, as recited in claim 26; a transducer with a heater component that is configured to be biased against a thermal capacitor of a respiratory flow component, as recited in claim 27; a transducer with a heater component that includes a thick film heater, as recited in claim 28; or a transducer with a temperature sensor that senses a temperature of a heater component, a capacitor, or a luminescable composition, as recited in claim 30.

Independent claim 36 is allowable since neither Stanley nor Knodle teaches or suggests a transducer with a detector that is substantially stable for about eight hours or more. Additionally, Stanley and Knodle both lack any teaching or suggestion of a transducer with a detector that is oriented toward an exterior surface of a window of a respiratory flow component to direct

radiation directly through a thickness of the window to a luminescable composition adjacent to an opposite, interior surface of the window.

Claim 37, which is allowable for depending from claim 36, is also allowable because Stanley and Knodle both lack any teaching or suggestion of a transducer with a detector that “has a stability of about ± 2 torr over eight hours at an atmospheric oxygen concentration.”

It is, therefore, respectfully submitted that a *prima facie* case of obviousness has not been established against any of claims 1-10, 13-15, and 17-35. Therefore, under 35 U.S.C. § 103(a), the subject matter recited in each of claims 1-10, 13-15, and 17-35 is allowable over the subject matter taught in Stanley and Knodle.

It is also respectfully submitted that, without the benefit of hindsight that the claims of the above-referenced application have provided to the Office, there wouldn’t have been any apparent reason for one of ordinary skill in the art to combine teachings from Stanley and Knodle in the manner that has been asserted by the Office. Without such knowledge, one of ordinary skill in the art wouldn’t have been motivated to combine teachings that relate to the oxygen sensor of Stanley with a pass-through carbon dioxide sensor of Knodle in the manner that has been asserted.

In particular, the claims of the above-referenced application are directed to transducers. As the side stream monitoring apparatus of Stanley does not include a transducer, the Office has relied upon Knodle for its disclosure of a multi-component respiratory sensor that includes a transducer that is configured for assembly with a “mainstream” cuvette. It is respectfully submitted that one of ordinary skill in the art wouldn’t have been motivated to add complexity to the integral side stream, luminescence quenching type oxygen monitoring apparatus of Stanley by incorporating various components thereof into a separate transducer and cuvette, particularly from an attenuated radiation type carbon dioxide sensor of the type taught in Knodle.

It is further submitted that one of ordinary skill in the art would have understood the inventive effort required to adapt a luminescence quenching type sensor from the context of side stream monitoring, in which very small respiratory samples are used, to a mainstream device, in which monitoring is conducted on a much large sample – all respiratory gases.

Furthermore, one of ordinary skill in the art wouldn't have been motivated to combine teachings from a luminescence quenching apparatus of the type taught in Stanley with teachings that pertain to an infrared sensing device, such as that taught in Knodle. In the luminescent quenching apparatus of Stanley, radiation emitted from a source follows an obstructed path, which terminates at a luminescable material, and different radiation emitted by the luminescable material is sensed by a detector. In contrast, the infrared sensing device of Knodle requires an unobstructed path so that radiation emitted from a source may be sensed by a detector.

Additionally, it is respectfully submitted that there would have been no reason for one of ordinary skill in the art to have expected that the purported combination of teachings from Stanley and Knodle would have been successful, particularly when the teachings of these references are considered in their entirieties, as required by M.P.E.P. § 2141.02. For example, the luminescent material-coated tube, sensor, and detector of Stanley are part of an integral unit; thus, there would be no reason to couple the transducer of Knodle to the apparatus of Stanley. Even assuming, for the sake of argument, that the transducer of Knodle could be coupled to the apparatus of Stanley, the wavelengths that are generated and detected by the source and detector of Knodle's transducer would not excite the luminescent material within the apparatus of Stanley or detect fluorescence from the luminescent material.

Further, the presence of luminescable material on the surfaces of the tube would interfere with the transmission of infrared radiation completely through the tube, as would be required for the transducer taught in Knodle to work with the sample tube of Stanley. Therefore, one of ordinary skill in the art would not have any reason to expect that features from the mainstream infrared sensor taught in Knodle could be incorporated into the side stream luminescence quenching sensor taught in Stanley.

Stanley, Knodle, and Yafuso

Claims 11 and 12 are rejected under 35 U.S.C. § 103(a) for being drawn to subject matter that is allegedly unpatentable over the teachings of Stanley, in view of teachings from Knodle

and, further, in view of the subject matter taught in U.S. Patent 4,849,172 to Yafuso et al. (hereinafter "Yafuso").

Yafuso does not remedy the aforementioned deficiencies of Stanley and Knodle. Therefore, claims 11 and 12 are both allowable, among other reasons, for respectively depending directly and indirectly from claim 1, which is allowable.

Stanley, Knodle, and Hauenstein

Claim 16 has been rejected under 35 U.S.C. § 103(a) for being drawn to subject matter which is assertedly unpatentable over that taught in Stanley, in view of teachings from Knodle and, further, in view of the teachings of U.S. Patent 4,861,727 to Hauenstein et al. (hereinafter "Hauenstein").

Hauenstein does not remedy the aforementioned deficiencies of Stanley and Knodle. Therefore, claim 16 is allowable, among other reasons, for depending directly from claim 1, which is allowable.

Stanley, Knodle, and Alcala

Claim 38 stands rejected under 35 U.S.C. § 103(a) for being reciting subject matter that is allegedly unpatentable over the teachings of Stanley, in view of teachings from Knodle and, further, in view of the teachings of U.S. Patent 5,315,993 to Alcala et al. (hereinafter "Alcala").

It is respectfully submitted that none of Stanley, Knodle, or Alcala teaches or suggests a transducer with a source and detector that are oriented toward an exterior surface of the same area of the same window of a respiratory flow component, as recited in independent claim 38, as proposed to be amended herein.

Furthermore, Alcala does not remedy any of the other aforementioned deficiencies of Stanley and Knodle in supporting a *prima facie* case of obviousness against independent claim 38.

It is respectfully requested that the 35 U.S.C. § 103(a) rejections of claims 1-38 be withdrawn, and that each of these claims be allowed.

Entry of Amendments

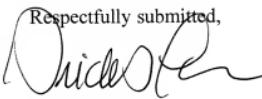
It is respectfully requested that the proposed amendments be given sufficient consideration that a determination may be made as to whether they place any of the claims in condition for allowance or reduce the number of issues that remain for purposes of appeal. M.P.E.P. § 714.13(III).

Entry of the proposed claim amendments is respectfully solicited. It is respectfully submitted that none of the proposed claim amendments introduces new matter into the above-referenced application, and it is not believed that their entry would necessitate another search. It is also believed that the proposed claim amendments eliminate all of the issues that remain for purposes of appeal.

In the event that a decision is made not to enter the proposed claim amendments, their entry upon the filing of a Notice of Appeal in the above-referenced application is respectfully requested.

CONCLUSION

It is respectfully submitted that each of claims 1-38 is allowable. An early notice of the allowability of each of these claims is respectfully solicited, as is an indication that the above-referenced application has been passed for issuance. If any issues preventing allowance of the above-referenced application remain which might be resolved by way of a telephone conference, the Office is kindly invited to contact the undersigned attorney.

Respectfully submitted,


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